Applicant: Winthrop D. Childers et al.

Serial No.: 10/808,897 Filed: March 25, 2004

Docket No.: 200314128-1 (H301.367.101)

Title: CELL TRANSPORTER FOR A BIODEVICE

#### REMARKS

The following Remarks are made in response to the Non-Final Office Action mailed April 5, 2006, in which claims 1-8, 10-21, 23 and 24 were rejected, and claims 9 and 22 were objected to. With this amendment, claims 25-30 have been cancelled without prejudice, claims 1-19 and 21-23 have been amended, new claims 31-32 have been added, and objected to claims 9, 22, and 23 have been rewritten in independent allowable form. Claims 1-24 and 31-32, therefore, are pending in the application and are presented for consideration and allowance.

# Claim Rejections under 35 U.S.C. § 112

In the Office Action, claims 23 and 24 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, dependent claim 23 has been rewritten in independent form including the limitations from the base claim 19 and any intervening claims. Second, Applicant has further amended claim 23 regarding the respective roles of the traveling wave DEP field and the fluid flow pressure drop, thereby obviating the rejection under 35 U.S.C. 112. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of independent claim 23. Dependent claim 24 is believed to be allowable based on its dependency from patentably distinct claim 23.

### Claim Rejections under 35 U.S.C. § 102

In the Office Action, claims 1-8, 19 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Becker et al. US Patent No. 5,993,632 (the Becker Patent).

Applicant's amended independent claim 1 is directed to a biodevice. The biodevice comprises an array of operative stations and a transporter configured for transporting cells during a transport time period. Each respective operative station is configured for performing an operation on the cells. The transporter is in fluid communication with the at least one of the respective operative stations and is independent of (and separate from) the respective operative stations.

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In contrast, the Becker Patent discloses a method and apparatus for the discrimination of particulate matter, including separation, characterization, differentiation and manipulation of the particulate matter. See the Becker Patent at Column 2, lines 36-50. Particles may be distinguished by differences in their density, size, dielectric permittivity, electrical conductivity, surface charge, and/or surface configuration. See the Becker Patent at Column 2, lines 59-62. In addition, the Becker Patent discloses various aspects of cDEP forces, twDEP forces and field flow fractionation for accomplishing these goals.

The Becker Patent describes these forces and their effects on cells in the context of discrimination and separation, rather than transportation as claimed by Applicant in claim 1. Accordingly, the Becker Patent fails to disclose a transporter that is in fluid communication with the at least one of the respective operative stations (e.g., sorter, filter, etc.) and that is independent of (and separate from) the respective operative stations, as claimed by Applicant in claim 1.

Accordingly, by focusing on characterization and separation, the Becker Patent also fails to describe a motion-inducing apparatus that induces transportation along the cell transport path between operative stations (e.g. a sorter, filter, etc.) of a biodevice, as claimed by Applicant in claim 1.

In further contrast, the Becker Patent fails to disclose a transport control unit to, among other things, induce a secondary motion of the cells to discourage aggregation of the cells during transportation of the cells on the transport path without performing an operation on the cells via the respective operative stations, as claimed by Applicant in claim 1. Instead, the Becker Patent effectively focuses on discrimination and separation of cells rather than transportation of the cells to or from an operative station (e.g., a sorter). Because the Becker Patent focuses on discriminating or separating cells, the Becker Patent appears to ignore discouraging aggregation of the cells during the transport of cells (without characterizing or separating the cells).

For these reasons, the Becker Patent fails to teach or suggest Applicant's amended independent claim 1, and therefore claim 1 is patentable and allowable over the Becker Patent.

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Dependent claims 2-8 and 10-18 are also believed to be allowable based on their dependency from patentably distinct claim 1 and for the reasons presented below relative to each respective dependent claim.

Applicant's amended independent claim 19 specifies an apparatus for moving cells on an electronic biodevice between operative stations on the biodevice during a transport time period. The apparatus comprises means for imparting a primary motion of the cells on the biodevice along a cell transport path to transport the cells between the operative stations on the biodevice, and a secondary motion of the cells to substantially prevent aggregation of the cells during the cell transport on the cell transport path, wherein the means for imparting is independent of and separate from the operative stations that are in fluid communication with the cell transport path. The apparatus also comprises a means for controlling the means for imparting, via control signals, to selectively activate the primary motion to move the cells along the cell transport path and to selectively activate the secondary motion to maintain substantially aggregation-free transport of the cells without sorting the cells along the cell transport path during the transport time period.

In contrast, the Becker Patent discloses a method and apparatus for the discrimination of particulate matter, including separation, characterization, differentiation and manipulation of the particulate matter. See the Becker Patent at Column 2, lines 36-50. Particles may be distinguished by differences in their density, size, dielectric permittivity, electrical conductivity, surface charge, and/or surface configuration. See the Becker Patent at Column 2, lines 59-62. In addition, the Becker Patent discloses various aspects of cDEP forces, twDEP forces and field flow fractionation for accomplishing these goals. The Becker Patent describes these forces and their effects on cells in the context of discrimination and separation, rather than transport.

Accordingly, the Becker Patent fails to disclose an apparatus for moving cells on an electronic biodevice between operative stations on the biodevice during a transport time period in which a means for imparting a primary motion and a secondary motion is in fluid communication with the respective operative stations and that is independent of (and separate from) the respective operative stations, as claimed by Applicant in claim 1.

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Moreover, the Becker Patent fails to disclose a means for controlling the means for imparting, via control signals, to selectively activate the primary motion to move the cells along the cell transport path and to selectively activate the secondary motion to maintain substantially aggregation-free transport of the cells without sorting the cells along the cell transport path during the transport time period.

Instead, the Becker Patent effectively focuses on discrimination and separation of cells rather than transportation of the cells to or from an operative station (e.g., a sorter), as claimed by Applicant in claim 19. Because the Becker Patent focuses on discriminating or separating cells, the Becker Patent appears to ignore maintaining substantially aggregation-free transport of cells during the transportation of cell without sorting the cells.

For these reasons, the Becker Patent fails to teach or suggest Applicant's amended independent claim 19, and therefore claim 19 is patentable and allowable over the Becker Patent.

Dependent claims 20-21 are also believed to be allowable based on their dependency from patentably distinct claim 19 and for the reasons presented below relative to each respective dependent claim.

In the Office Action, claims 1-4, 6 and 19 were rejected under 35 U.S.C. 102(b) as being anticipated by Crane et al.US Patent No. 5,489,506 (the Crane Patent).

Applicant's amended independent claim 1 is directed to a biodevice. The biodevice comprises an array of operative stations and a transporter configured for transporting cells during a transport time period.

The Crane Patent discloses a method and apparatus for <u>continuously sorting</u> living cells (the Crane Patent Abstract) that includes an expansion chamber 24 including a series of field electrodes (RF-1, RF-2, and RF-3) for applying signals of different frequencies to sort cells moving through chamber 24. By adjusting the frequency, signal strength, and varying the electrodes used, <u>sorting</u> is accomplished with considerable definiteness and differentiation. See the Crane Patent at Column 6, lines 23-54.

Accordingly, in contrast to Applicant's claim 1, the Crane Patent fails to disclose a transporter for transporting cells on an electronic biodevice between operative stations on the biodevice during a transport time period in which the transporter, including a motion-

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inducing apparatus to induce transportation of the cells, is in fluid communication with the respective operative stations and that is independent of (and separate from) the respective operative stations, as claimed by Applicant in claim 1.

In further contrast, the Crane Patent fails to disclose a transport control unit to, among other things, induce a secondary motion of the cells to discourage aggregation of the cells, without performing an operation on the cells via the at least one operative station, during transportation of the cells via the transporter.

For these reasons, the Crane Patent fails to teach or suggest Applicant's amended independent claim 1, and therefore claim 1 is patentable and allowable over the Crane Patent.

Dependent claims 2-4 and 6 are also believed to be allowable based on their dependency from patentably distinct claim 1 and for the reasons presented below relative to each respective dependent claim.

Applicant's amended independent claim 19 specifies an apparatus for moving cells on an electronic biodevice between operative stations on the biodevice during a transport time period.

In contrast, the Crane Patent discloses a method and apparatus for <u>continuously</u> sorting living cells (the Crane Patent Abstract) that includes an expansion chamber 24 including a series of field electrodes (RF-1, RF-2, and RF-3) for applying signals of different frequencies to sort cells moving through chamber 24. By adjusting the frequency, signal strength, and varying the electrodes used, <u>sorting</u> is accomplished with considerable definiteness and differentiation. See the Crane Patent at Column 6, lines 23-54.

Accordingly, the Crane Patent fails to disclose an apparatus for moving cells on an electronic biodevice between operative stations on the biodevice during a transport time period in which a means for imparting a primary motion and a secondary motion is in fluid communication with the respective operative stations and that is independent of (and separate from) the respective operative stations, as claimed by Applicant in claim 19.

Moreover, the Crane Patent fails to disclose a means for controlling the means for imparting, via control signals, to selectively activate the primary motion to move the cells along the cell transport path and to selectively activate the secondary motion to maintain

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substantially aggregation-free transport of the cells without sorting the cells along the cell transport path during the transport time period.

Instead, the Crane Patent effectively focuses on sorting cells rather than transportation of the cells to or from an operative station (e.g., a sorter). Because the Crane Patent focuses on sorting cells, the Crane Patent appears to ignore maintaining substantially aggregation-free transport of cells during the transport of cell without sorting the cells.

For these reasons, the Crane Patent fails to teach or suggest Applicant's amended independent claim 19, and therefore claim 19 is patentable and allowable over the Crane Patent.

In the Office Action, claims 1-4 and 19-21 were rejected under 35 U.S.C. 102(b) as being anticipated by Lock et al. WO 01/05514 A1 (the Lock Publication).

Applicant's amended independent claim 1 is directed to a biodevice. The biodevice comprises an array of operative stations with each respective operation station configured to perform an operation on the cells, and a transporter configured for transporting cells during a transport time period. The transporter is in fluid communication with the at least one of the respective operative stations and is independent of (and separate from) the respective operative stations.

In contrast, the Lock Publication discloses a method of traveling wave dielectrophoresis that is primarily applied to the simultaneous application of two different frequencies to characterize or separate cells. In addition, the Lock Publication discloses various aspects of using twDEP forces and other forces for accomplishing these goals See the Abstract of the Lock Publication and the Lock Publication at Page 20, lines 6-34; Page 1; Page 4, lines 1-10; Page 11, lines 4-20; Page 14, lines 8-14 and 33-37; Page 16, lines 21 and 36; Page 17, lines 3-16; and claim 1.

However, the Lock Publication describes these forces and their effects on cells in the context of <u>characterization</u> and <u>separation</u> but <u>not</u> transportation in the manner claimed by Applicant in claim 1 in which the cells are transported (on the cell transport path during the transport time period) via (1) a primary motion between respective operative portions of the biodevice and (2) a secondary motion to discourage aggregation of cells without performing an operation on the cells.

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In further contrast to Applicant's claim 1, with a focus on characterization and separation of cells, the Lock Publication fails to disclose a transporter that is in fluid communication with the at least one of the respective operative stations and that is independent of (and separate from) the respective operative stations (e.g., a sorter, a filter, etc.) and having the features specified in the limitations of claim 1.

For these reasons, the Lock Publication fails to teach or suggest Applicant's amended independent claim 1, and therefore claim 1 is patentable and allowable over the Lock Publication.

Dependent claims 3-4 are also believed to be allowable over the Lock Publication based on their dependency from patentably distinct claim 1 and for the reasons presented below relative to each respective dependent claim.

Applicant's amended independent claim 19 specifies an apparatus for moving cells on an electronic biodevice between operative stations on the biodevice during a transport time period.

In contrast, the Lock Publication discloses a method of traveling wave dielectrophoresis that is primarily applied to the simultaneous application of two different frequencies to characterize or separate cells. In addition, the Lock Publication discloses various aspects of using twDEP forces and other forces for accomplishing these goals See the Abstract of the Lock Publication and the Lock Publication at Page 20, lines 6-34; Page 1; Page 4, lines 1-10; Page 11, lines 4-20; Page 14, lines 8-14 and 33-37; Page 16, lines 21 and 36; Page 17, lines 3-16; and claim 1.

However, the Lock Publication describes these forces and their effects on cells in the context of <u>characterization</u> and <u>separation</u> but <u>not</u> transportation in the manner claimed by Applicant in claim 19 in which the cells are transported via a means for imparting (on the cell transport path during the transport time period) via (1) a primary motion between respective operative portions of the biodevice and (2) a secondary motion to maintain substantially aggregation-free transport of cells along the cell transport path.

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Accordingly, the Lock Publication fails to disclose an apparatus for moving cells on an electronic biodevice between operative stations on the biodevice during a transport time period in which a means for imparting a primary motion of the cells (along a cell transport path to transport the cells between the operative stations on the biodevice) and a secondary motion (to prevent aggregation of the cells during the cell transport on the cell transport path) is in fluid communication with the respective operative stations and that is independent of (and separate from) the respective operative stations, and having the features specified in the limitations of claim 19.

Moreover, the Lock Publication fails to disclose a means for controlling the means for imparting, via control signals, to selectively activate the primary motion to move the cells along the cell transport path and to selectively activate the secondary motion to maintain substantially aggregation-free transport of the cells without sorting the cells along the cell transport path during the transport time period.

Instead, the Lock Publication effectively focuses on characterization and separation of cells rather than transportation of the cells to or from an operative station (e.g., a sorter).

Because the Lock Publication focuses on discriminating or separating cells, the Lock

Publication appears to ignore maintaining substantially aggregation-free transport of cells during the transport of cell and without sorting the cells.

For these reasons, the Lock Publication fails to teach or suggest Applicant's amended independent claim 19, and therefore claim 19 is patentable and allowable over the Lock Publication.

Dependent claims 20-21 are also believed to be allowable over the Lock Publication based on their dependency from patentably distinct claim 19.

Accordingly, Applicant respectfully requests that the above 35 U.S.C. § 102(b) rejection to claims 1-8 and 19-21 based on the Becker Patent, the Crane Patent, or the Lock Publication be reconsidered and withdrawn, and that these claims be allowed.

### Claim Rejections under 35 U.S.C. § 103

In the Office Action, claims 10-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Becker Patent.

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First, claims 10-18 depend from patentably distinct independent claim 1, which is believed to be allowable over the Becker Patent for the reasons previously stated.

Second, Applicant objects to the characterization of the claimed electrode arrangements as expressions of mere optimization, as the claimed electrode arrangements provide unique functions in the context of a transporter of a biodevice, unlike the various conventional combinations in the cited references.

Accordingly, Applicant respectfully requests that the above 35 U.S.C. § 103(a) rejection to claims 10-18 based on the Becker Patent be reconsidered and withdrawn, and that these claims be allowed.

# Allowable Subject Matter

In the Office Action, claims 9 and 22 were objected to but indicated to be allowable if rewritten in independent form. Applicant presents amended claims 9 and 22 that have been rewritten into allowable independent form, including all of the limitations of the base claim and any intervening claims. Accordingly, Applicant respectfully requests allowance of amended independent claims 9 and 22.

In the Office Action, claims 23 and 24 were indicated to be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims. As previously described above, claims 23 and 24 were rewritten to obviate the Section 112 rejection and into allowable independent form. Accordingly, Applicant respectfully requests allowance of claims 23 and 24.

# **New Claims**

New claims 31 and 32 are presented for consideration and are believed to be allowable. Favorable consideration is respectfully requested.

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## CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-24 and 31-32 are all in a condition for allowance and requests reconsideration of the application and allowance of all pending claims.

Any inquiry regarding this Amendment and Response should be directed to either Donald J. Coulman at Telephone No. (541) 715-1694, Facsimile No. (541) 715-8581 or Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

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CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this paper or papers, as described herein, are being facsimile transmitted to the United States Patent and Trademark Office, Fax No. (571) 273-8300 on this 2046 day of June, 2006.

Name: Paul S. Grunzweig